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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/358,788	07/22/1999	MICHAEL J. HELLER	ELI-0020C3 (130101.00025)	1976
25555	7590	04/20/2010	EXAMINER	
JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202-3797			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
			04/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/358,788	Applicant(s) HELLER ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,57,58 and 79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49,57,58 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 24 March 2010 in which claim 49 was amended and claim 79 was added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 24 September 2009 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendment, are discussed.

Claims 49, 57, 58 and 79 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 49, 57, 58 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 49 has been amended to define a "mobilized probe" wherein the probe comprises an oligonucleotide sequence that hybridizes to the target.

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Applicant points to page 10, lines 2-8; page 12, line 30-page 13, line 13; page 29, lines 12-23; and page 33, lines 1-15 for support of the newly defined probe.

The passages on pages 10, 12-13 and 29 discuss electronic transportation of analyte or reactant molecules to and from specific micro-locations. These passages do not describe contacting an anchor probe with a sample oligonucleotide and mobilized probe as newly claimed. The passage at page 33 describes electronically controlled hybridization comprising electronically concentrating sample nucleic acids at micro-locations having capture probes wherein “reporter probes are hybridized in subsequent steps to detect hybridized complexes”. This passage merely states that the probes are hybridized in subsequent steps, but the passage does not define what the reporter probes hybridize to so as to define a mobilized probe complementary to the target. Furthermore, the passage does not define a single step of anchor, target and reporter complex formation. While this passage describes transport of “reporter probes”, the passage does not define reporter probes having properties of the instantly claimed mobilized probe. The specification was reviewed for a definition or discussion of reporter probes. However, no such discussion was found. Hence, the newly defined “mobilized probe” appears to introduce subject matter which was not disclosed in the originally filed specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 49, 57, 58 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al (U.S. Patent No. 5,846,708, filed 23 April 1992) in view of Dattagupta (U.S. Patent No. 4,777,129, issued 11 October 1988) or Wang et al (U.S. Patent No. 4,925,785, issued 15 May 1990).

Regarding Claims 49 and 79, Hollis teaches a method for analyzing a sample oligonucleotide, the method comprising forming a plurality of test sites on a substrate (Column 4, lines 32-45) wherein each test site is electronically addressable (Column 5, lines 6-18), electronically immobilizing oligonucleotide anchor sequences to individually selected locations (Column 13, lines 8-63), contacting the sample oligonucleotide with the immobilized probe for hybridization and subjecting the hybrids from to a reverse bias potential to remove unbound oligonucleotides (Column 13, line 64-Column 14, line 19) and detecting hybridization (Column 4, lines 46-67). Hollis teaches the method wherein the sample solution is electronically transported to the locations (Column 14, lines 1-19) but does not teach that the solution contains a mobilized probe in combination with the target oligonucleotide. However, mobile probes forming a sandwich complex with the target and anchor probe were well known and routinely practiced in the art at the time the invention was made as taught by Dattagupta and Wang.

Dattagupta teaches applying mobile probes and complementary to the target to immobilized capture probes (Column 15, lines 5-15 and Claim 12). Dattagupta further teaches that the mobile probes provide greater number of labels per target nucleic acid

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thereby greatly increasing detection sensitivity (Column 15 and Claim 12). Wang also teaches mobile probes and target molecules in solution applied to an immobilized capture probe forming a sandwich complex (Fig. 6, Example 1, Column 14). Wang also teaches a sandwich complex and the advantages provided (Column 2):

In addition to the divalency conferred upon the target DNA in sandwich hybridizations, other advantages result. For example, one of the probes (P.sub.1), can be bound to the planar filters by the manufacturer of the diagnostic kit. Thus, location of the spot on the filter, the area which the spot covers, and the amount of probe bound to the spot can be carefully controlled by the manufacturer to help eliminate variability in the test results and to aid in automating the tests. The precise spotting of P.sub.1 on the filter then directs precisely the target DNA carrying a labelled P.sub.2 probe DNA to the filter spot. Furthermore, the manufacturer has carried out many of the user's steps, making the test easier to use. (emphasis added)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the mobile probes and sandwich hybridization of Dattagupta and/or Wang to the hybridization methods of Hollis. One of ordinary skill in the art would have been motivated to do so for the well known benefits taught by Dattagupta and/or Wang.

Regarding Claim 57, Hollis teaches the method further comprising subjecting the oligonucleotide to a field to attract it to the immobilized probe (Column 14, lines 6-14).

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Regarding Claim 58, Hollis teaches the method wherein the probe is 6 to 100 bases (Example 1, Column 16, line 10).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 49, 57-58 and 79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No.

6,051,380 in view of Dattagupta (U.S. Patent No. 4,777,129, issued 11 October 1988)

or Douglas (U.S. Patent No. 5,556,748, filed 30 July 1991).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to nucleic acid sample analysis using electronic transport and hybridization to a plurality of micro-locations. The claims sets merely differ in the arrangement of limitations within the sets. For example,

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independent claim 49 of the instant claims defines application of an electric field to remove unbound sample while dependent claim 10 of the '380 defines electronic stringency to remove unbound sample. The claim sets further differ in that the '380 claims define additional elements e.g. buffer compositions. However, the open claim language of the instant claims encompassed the additional element of the '380 claims. The claim sets further differ in that the instant claims are further drawn to adding a mobile probe along with the target to form a sandwich hybridization complex.

However, mobile probes forming a sandwich complex with the target and anchor probe were well known and routinely practiced in the art at the time the invention was made as taught by Dattagupta and Wang.

Dattagupta teaches applying mobile probes and complementary to the target to immobilized capture probes (Column 15, lines 5-15 and Claim 12). Dattagupta further teaches that the mobile probes provide greater number of labels per target nucleic acid thereby greatly increasing detection sensitivity (Column 15 and Claim 12). Wang also teaches mobile probes and target molecules in solution applied to an immobilized capture probe forming a sandwich complex (Fig. 6, Example 1, Column 14). Wang also teaches a sandwich complex and the advantages provided (Column 2, see above).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the mobile probes and sandwich hybridization of Dattagupta and/or Wang to the patent methods. One of ordinary skill in the art would have been motivated to do so for the well known benefits taught by Dattagupta and/or Wang.

Response to Arguments

8. Applicant argues that Hollis does not teach the mobile probes as newly claimed. The argument is deemed moot in view of the new grounds for rejection as discussed above.

Applicant argues that the instant claims are patentably distinct from the patent claims. Applicant asserts that the patent claims do not disclose or suggest 1-forming a plurality of locations; 2- electronically immobilizing one (or more) anchor sequences to the locations; 3- contacting a sample oligonucleotide and mobile probe forming a complex; and 4- subjecting the complex to an electric field to remove unbound sequences.

The argument is not found persuasive for the following reasons. Claim 5 of the patent defines the electronic matrix having a plurality of microlocations including probes and applying current to the matrix. While the claim does not define a method step of "forming", the electronic matrix could not be used in the patent method without formation. Therefore, the patent method inherently includes matrix formation. Furthermore, the "electronically immobilizing" is encompassed by the application of current and transport of nucleic acids. Additionally, Claim 10 of the patent is drawn to electronic stringency, which clearly encompasses applying an electric field to remove unbound sequences as instantly claimed. Finally, the newly defined mobile probes are obvious in view of the teaching of Dattagupta and Wang as discussed above. For all

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the above reasons, it is maintained that the instant claims are not patently distinct from the patent claims.

Conclusion

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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